UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,980	07/31/2003	Christopher J. Calhoun	MA9604P	2197

7590 02/06/2008

Stout, Uxa, Buyan & Mullins, LLP
Suite 300
4 Venture
Irvine, CA 92618

EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
02/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,980	CALHOUN ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32 and 53-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Remarks' filed 27 August 2007 have been acknowledged and duly made of record.

The arguments directed to the 112, 2nd paragraph rejection has been reconsidered in light of the explanation disclosed within the Remarks (pgs 1 and 2) and has thereby been withdrawn.

However, the arguments directed toward the 103(a) rejection, though considered are not found reasonably persuasive.

Applicants' cite in instant specification, thus:

In a presently preferred embodiment, the thin membranes can be manufactured using 25 extrusion procedures, such as for example those known in the art. **The extrusion procedures advantageously can provide for efficient production of the membranes.** Moreover, membranes, which are manufactured by such extrusion techniques can be free from solvent trappings in the membrane and, furthermore, can be provided with a molecular bias, including a predetermined molecular bias. Monoaxial extrusion may be employed to manufacture the membranes in a preferred embodiment of the present invention. **In a modified embodiment, biaxial extrusion procedures may be implemented to manufacture the membranes.** In one embodiment, a composition mixture comprising an amorphous resorbable polymer, such as an amorphous lactide polymer, which can be for example poly L-lactide or more preferably poly (L-lactide-co-D,L- lactide), is extruded to form a membrane of the present invention. In one embodiment, poly (L- lactide-co-D,L-lactide) 70:30 **Resomer LR708** (manufactured and supplied from Boehringer Ingelheim KG of Germany) is extruded to form membranes of the present invention.

The disclosure cited *supra* is a direct admission that the limitations as disclosed within the instant claims in regard to variable thickness, viscosity properties, and axes is readily reproducible by the 70:30 Resomer LR 708. The skilled artisan would instantly recognize a reasonable expectation drawn to the variable limitations in the present claims.

Accordingly, the instant specification is absent of any description, definition, and/ or explanation drawn to the inventive objective of the claimed invention. The applicants' disclose limitations within the instant claims, which are not so evident in view of the entire specification. The instant specification alleges an improved resorbable thin membrane that can be used in various surgical contexts. Then the applicants' disclose details of a specific extrusion process which requires direct specific parameters by which the viscosity property is the determinant as to the property by which the inventive objective is directed. In view of this, the skilled artisan would at once see the reasonable reproducibility drawn to obviousness over claimed invention. In other words, the viscosity property factor is the crux or central issue of the versatile nature that the amorphous polylactide material may assume.

Furthermore, applicants' disclosure contained within pages 6-13 would make it apparent to the skilled artisan that these embodiments would be reasonably common (in addition to the well-established knowledge in the art associated with extrusion processes of amorphous polylactide) in view of due experimentation.

Particularly, applicants' cite an explanation of the term "viscosity property" (page 6, 2nd paragraph) and then disclose that the central issue of applicants' discovery entails an amorphous polylactide composition which due to unprecedented experimentation (page 6, 3rd paragraph),

now is phenomenally produced in such a way as to increase therapeutic effect for which it is indicated.

The instant invention discloses a viscosity property of about 1 g/dL. In Example 4 (column 12, lines 44-51), the inherent viscosity of this polymer is 0.6 to 1.1 dl/g (Totakura et al. (USPN 5795584).

However, applicants' fail to essentially address the inventive significance of these alleged limitations via evidence (comparative analysis representation) within the specification and the instant claims. The burden, thus, lies with the applicants' to elucidate the phenomenon of this discovery via representative models and/or examples which clearly show a distinctness of invention in light of what is already known in the art or that which could be readily reproduced due to routine experimentation.

Still further, instant claims 23 and 24 are drawn to shrinking characteristics of the amorphous polylactide, which are both dependent from instant claim 3 which is ultimately dependent from base claim 1. Accordingly, based on the said disclosure, an amorphous polylactide, when infused with certain adjustments and refinements directed to due experimentation is naturally going to produce certain rate-limiting or specialized characteristics. in view of the above, the skilled artisan would instantly recognize routine experimentation embodied by manipulative processes which began initially from the preparatory processes of the amorphous polylactide itself. In other words, the material of amorphous polylactide is of such a malleable nature, that the material may be prepared (scientifically engineered) in such a way, i.e., viscosity properties, porosity diameter, that the predetermined effect is readily achieved.

The remainder of the specification is devoted to extrapolations devoid of a comparative, correlative, or representative data that would clearly point out that the inventor is in possession of the alleged invention.

Accordingly, the limitations as incorporated in the instant claims 53-55 do not introduce new matter in view of the current specification and are thus made obvious via the responses to applicants' arguments. As discussed above, the central issue of the inventive objective intended within instant claims 53-55 is ultimately drawn to the viscosity property factor and extrusion process manipulations, which are well-known in the art.

For the reasons already made of record, the Examiner maintains the rejection under 35 U.S.C. § 103(a) over Totakura et al. (U.S. Patent No. 5,795,584) and Vyarkarnam et al. (U.S. Patent No. 6,333,029) and Tang et al. (U.S. Patent No. 5,412,068), and rejected claims 6-10, 13 and 14 as being unpatentable under 35 U.S.C. § 103(a) over Totakura et al., Vyarkarnam et al. and Tang et al. as applied to claims 1-5, 15-17, and 19-32, and further ha view of Lemperle et al. (U.S. Patent No. 6,391,059), Lemperle et al. (U.S. Patent No. 6,280,473), and Mansmann, K. (U,S. Patent No. 6,530,956).

Thus, the deficiencies that the applicants' cite as inherent in the references *supra* are cured by properties, characteristics, susceptibilities, and manipulative processes that are well-known in the art that produce and which are produced from further characterization optimizations encompassed by routine experimentation.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Instant claims 1-32 and 53-55 are currently pending for further prosecution on the merits. Instant claims 53-55 have been newly added.

Claim Rejection- 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 11, 12, 15-17, 18, 19-32 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al. (USPN 5795584) and Vyarkarnam et al (USPN 6333029) Browall et al. (USPN 3,874,986) in view of Baars et al. and Tang et al. (USPN 5412068).

Totakura et al. teach surgical adhesion barriers and methods of using such surgical adhesion barriers. Surgical adhesion barriers according to the present invention have at least one layer of a bioabsorbable material comprising copolymers and/or block copolymers derived from trimethylene carbonate. Alternatively, a multilayer surgical structure having one or more bioabsorbable layers superimposed on a non-absorbable layer is useful for minimizing or preventing formation of fibrous adhesions between a healing trauma site and adjacent surrounding tissue. Alternatively, a bioabsorbable non-woven fabric in adherent contact with at least one bioabsorbable layer of foam, film, mesh, web or woven fabric is also provided. One or

more medicinal agents may be interposed between or disposed within any of the aforementioned layers (abstract only).

Totokura et al. teach non-porous non-absorbable layered membrane. The disclosure of non-permeability is an essential element, which is also central to claimed invention. Totokura et al. teach lactide and epsilon caprolactone. Further, Totokura et al. teach a viscosity property of 0.9: A 20/80 mole percent glycolide/trimethylene carbonate copolymer was prepared in a reactor by combining previously dried 53.13 grams of glycolide and 186.87 grams of trimethylene carbonate and polymerizing at 160.degree. C. for 24 hours in the presence of 0.05 grams of stannous octoate. The polymer was extruded from the reactor and post treated to remove any residual monomer present in the polymer. **The inherent viscosity of the polymer was 0.9** (column 11, line 44-51).

The instant invention discloses a viscosity property of about 1 g/dL. In Example 4 (column 12, lines 44-51), the inherent viscosity of this polymer is 06 to 1.1 dl/g. Additionally, the Examples teach thickness ranges of membranes from 1 cm X 2 to 2 cm X 3 cm (columns 11-18).

These ranges do not specifically read on the particular ranges as disclosed within the instant specification but do encompass the ranges as disclosed. Applicants' specifically disclose:

Furthermore, the Examiner further alleges in the same paragraph c.-the Office Action that Totokura et al. discloses ranges that "encompass the ranges disclosed in ['sic] subject invention." Applicants find no logic or basis for this statement. In any event, to the extent that Totokura et al. teaches thickness ranges of membranes from l cm x 2 to 2 cm x 3 cm, as alleged by the Examiner, Applicants respectfully submit that these ranges arc not encompassed by the presently claimed invention. In particular, the range of "0.001 mm to about 0.300 ram" in Applicants' independent claim 1 converts to a range of 0.0001 cm to -03 cm, and the range of "about 0.010 mm to about 0.030 mm: in Applicants' independent claim 25 converts to a range of 0.001 cm to about 0-003 cm. Neither of these claimed ranges are encompassed by the Totokura et al. numbers of 1 cm x 2 to 2 cm x 3 cm.

Totakura et al. does not specifically teach distinctions between membrane layers in terms of differences in mm.

Vyarkarnam et al. teach a three-dimensional inter-connected open cell porous foams that have a gradient in composition and/or microstructure through one or more directions. These foams can be made from a blend of absorbable and biocompatible polymers that are formed into foams having a compositional gradient transitioning from predominately one polymeric material to predominately a second polymeric material. These gradient foams are particularly well suited to tissue engineering applications and can be designed to mimic tissue transition or interface zones (Abstract).

Vyarkarnam et al. teach a poly-L-lactide, poly-DL-lactide (column 1, lines 39 and 40). Vyarkarnam et al. teach a mole ratio of epsilon caprolactone to p-dioxanone of from about from 30:70 to about 70:30) elastomeric copolymers of p-dioxanone and trimethylene carbonate (preferably having a mole ratio of p-dioxanone to trimethylene carbonate of from about 30:70 to about 70:30), elastomeric copolymers of trimethylene carbonate and glycolide (preferably having a mole ratio of trimethylene carbonate to glycolide of from about 30:70 to about 70:30), elastomeric copolymer of trimethylene carbonate and lactide including L-lactide, D-lactide, blends thereof or lactic acid copolymers (preferably having a mole ratio of trimethylene carbonate to lactide of from about 30:70 to about 70:30) and blends thereof (column 10, lines 60-67). Instant invention is drawn toward a 70:30 poly (L-lactide-co-D, L,-lactide) (pg 5).

Vyarkarnam et al. do not teach non-porous membranes.

However, Browall et al. does teach the ultrathin non-porous membranes for use in the practice of this invention are prepared by the Ward process by casting on a confined liquid surface. A pair of movable longitudinally-extending barriers initially spaced apart a small distance and in contact with the liquid surface are employed, first, to accommodate the casting solution there between and second by relative separation thereof to controllably permit spreading of the casting solution over the surface of the film-support liquid. Water is the preferred film support liquid (abstract only).

Totakura et al., Vyarkarnam et al. and Browall et al. do not specifically teach the limitations drawn to a bias toward one to two axes.

However, Baars et al. does teach the formation of thick films having a biaxial molecular orientation. Such films are prepared in accordance with the present invention from rod-like extended chain aromatic-heterocyclic ordered polymers. Such films have high tensile strength, modulus, and environmental resistance characteristics. A preferred ordered polymer for use in the present invention is poly (para-phenylenebenzo bisthiazole), (PBT), a compound having the structure [as disclosed]. The present invention is also directed to methods and apparatus suitable for producing biaxially oriented films, coatings, and like materials from ordered polymers, preferably PBT (abstract only).

Baars et al. further discloses the inventive objective and reasoning drawn to the preparation and process of manufacturing such polymers. The scientific engineering and manipulation of such polymers with variable sizes, widths, thicknesses, elongation requirements, smoothness, rigidity, etc. is well-suggested and supported in the present Baars et al. reference.

Accordingly, Tang et al. teach medical devices formed totally or in part from homopolymers or copolymers comprising recurring carbonate moieties (Abstract).

Tang et al. teach bioresorbable polymers, which are used in the fabrication of devices for implantation in living tissue for several decades. Medical application of such polymers includes absorbable sutures, haemostatic aids and, recently, intraosseous implants and control-release drug delivery systems.

Claims 6-10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al., Vyarkarnam et al., Browall et al., Baars et al. and Tang et al. as applied to claims 1-5, 11, 12, 15-17, 18, 19-32 and 53-55 above, and further in view of Lemperle et al. (USPN 6391059), Lemperle et al. (USPN 6280473), and Mansmann, K. (USPN 6530956).

Lemperle et al. (059) teach a resorbing flexible implant in the form of a continuous macro-porous sheet (42) is disclosed. The implant is adapted to protect biological tissue defects, especially bone defects in the mammalian skeletal system, from the interposition of adjacent soft tissues during in vitro repair. The membrane (42) has pores with diameters from 20 microns to 3000 microns. This porosity is such that vasculature, and connective tissue cells derived from the adjacent soft tissues including the periosteum, can proliferate through the membrane into the bone defect. The thickness of the sheet is such that the sheet has both sufficient flexibility to allow the sheet to be shaped to conform to the configuration of a skeletal region to be repaired, and sufficient tensile strength to allow the sheet to be so shaped without damage to the sheet. The sheet provides enough inherent mechanical strength to withstand pressure from adjacent musculature, and does not collapse (Abstract).

Lemperle et al. (059) teach a membrane capable of resorbing into the mammalian body within a period of 24 months from the initial implantation (column 6, lines 64-67), which is obvious over instant claim 1.

Lemperle et al. (059) teaches molecular orientation in regard to a single axis or axes (at least two), which is obvious over instant claim 7 of subject invention (column 14, line 1; line 43). Further, Lemperle et al. teach specific additives (column 5, lines 66-67), which is obvious over instant claim 13 of subject invention.

Lemperle et al. (059) does not teach the membrane thickness of about 0.001 mm to about 0.300 mm. Lemperle et al (059) does not teach sealed sterile packaging.

However, Lemperle et al (473) does teach membrane thickness ranges which fall within the instant ranges of 1 micron to 300 microns (column 3, line 62; column 6, lines 9 and 57-60), which is obvious over instant claim 1. Lemperle et al. (473) also teach a range which encompasses instant inventions highest range (column 16, line 9).

Additionally, Mansmann, K (USPN 6530956) does teach a resorbable scaffold contained in a sealed sterile package used to help transplanted chondrocytes or other cells generate new cartilage in a damaged joint (column 9, line 15), which is obvious over instant claim 14.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to recognize with a reasonable expectation of success via the combining and/or incorporating together the methods, compounds, and teachings of Totokura et al., Vyarkarnam et al., Browall et al., Baars et al and Tang et al. incorporated with the teachings of Lemperle et al. and Mansmann, K. The references *supra* in combination with interchangeable modifications embody and encompass the central elements of claimed invention as explained above. The motivation to combine is present in Totokura et al. which encompasses elements of Vyarkarnam et al. Vyarkarnam et al., in addition, teach elements that are not readily disclosed within

Totokura, but encompass further elements obvious over the instant claims and the subject invention. Browall et al. and Baars et al. cure the deficiencies of the other references as disclosed via explanations replete with embodiments which describe plethora of properties of an amorphous polylactide and/or non-porous membranes and derivatives thereof. In addition, Browall et al. and Baars et al. provide the most comprehensive motivation to combine all the references via insight into the actual scientific engineering which is readily reproducible and is well-established in the art of polymer manipulation. Lemperle et al. and Mansmann et al. are the motivation to further combine by encompassing the specific claim limitations of instant claims 6-14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

SHENGJUN WANG
PRIMARY EXAMINER